NOV 2 2 2000

Total Medical Information Management Systems, Inc.
407 Wekiva Springs Rd.
Suite 347
Longwood, Florida 32779
407-788-6353

K001947
Page 1 of 3

510 (k) Summary

1. Identification

Date Prepared:	June 1, 2000
Submitter:	Total Medical Information Management Sys., Inc 407 Wekiva Springs Rd. Suite 347 Longwood, Fl. 32779-6097
Contact:	Don Beavers, President Phone: 407-788-6353 Fax: 407-788-2476

2: Device Name

Proprietary Name:	*T.I.M.S.*
Common Name:	Teleradiology System
Classification Name:	Picture Archiving and Communication System

3: Regulatory Class

Class:	2
Panel:	Radiology
Product Code:	CFR 892.2050; LLZ

4. Predicate Device

Olicon 02 Workstation and/or PACSVIEW software; K973959
Images-On-Call Teleradiology System; K896095

K001947
Page 2 of 3

5. Device Description

The *T.I.M.S.* Teleradiology system is a general purpose software designed for the acquisition/capture/view/archival and transmission of medical images. The software operates on "off the shelf" hardware using a Windows 95 or higher platform. It is designed to capture, acquire, send, receive, archive and display patient images and data, using the DICOM communication standard. *T.I.M.S.* can be installed on a PC in the hospital, via a web-browser, and on a local LAN or WAN, and includes teleradiology, connectivity and display features. It employs the latest internet security techniques, including 128 bit encryption.

6. Indications for Use

T.I.M.S. receives image data, acquired from various sources, including but not limited to CT, MR, US, Nuclear, digital angiography and flourography, secondary capture devices (frame grabbers), scanners or other imaging sources. Images and data can be stored, transmitted (communicated), processed at the workstation, physician's desktop or other clinical application and distributed across networks or the world wide web.

7. Substantial Equivalence Comparison

T.I.M.S. is a medical imaging software device that is substantially equivalent to medical image software devices previously cleared and marketed under the names of Olicon 02-Workstation and/or PACSView software (K973959) and Images-On-Call teleragiology system (K896095). The predicate devices have the same intended use for the receipt of images and data from imaging modalities, secondary capture devices, scanners or imaging gateways. This device does not offer any new functions that have not received previous clearance from the Agency.

8. Safety and Effectiveness

T.I.M.S. software system is primarily used to capture/view/archive/transmit medical images. It does not require specialized or nonstandard devices of any type. Image acquisition and display is via the industry-standard DICOM 3 protocol, allowing the images to be produced the data originated by the imaging modality, either digital or analog. The software will operate on standard "off the shelf" hardware and system configurations. Similar to predicate devices it can be used with image compression. The lossy/lossless image compression libraries are believed to be substantially equivalent to the libraries used in previously cleared devises.

K001947
Page 3 of 3

The software is intended to provide the means for medical professionals to display data generated by medical scanning devices on a personal computer or workstation.

9. Conclusion

Similar to predicate devices, the *T.I.M.S.* system software does not contact the patient, or control any life sustaining devices. Images and information being reviewed, processed, relayed, and or transmitted are interpreted by a physician or trained medical personnel, providing ample opportunity for competent human intervention. In device failures which might result in partial or failed transmissions, the images and or data may be recovered by re-transmission after correcting the problems. Passwords are required for operation and to protect against unauthorized use of the system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2000

Don Beavers
President
Total Medical Information Management Systems, Inc.
407 Wekiva Spring Rd., Suite 347
Longwood, FL 32779-6907

Re: K001947
T.I.M.S. Version 2.00
Dated: October 2, 2000
Received: October 3, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90LLZ

Dear Mr. Beavers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510 (k) NUMBER (IF KNOWN): K001947

DEVICE NAME: T.I.M.S. TELERADIOLOGY SYSTEM

INDICATIONS FOR USE:

T.I.M.S. receives image data, acquired from various sources, including but not limited to CT, MR, US, Nuclear, digital angiography and flourography, secondary capture devices (frame grabbers), scanners (digitizers) or other imaging sources. Images and data can be viewed, stored, transmitted (communicated), processed at the workstation, physician's desktop or other clinical application and distributed across networks or the world wide web for viewing.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David A. Segstrom

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001947